REMARKS

Claims 7-9 were rejected under Section 101, the Examiner noting that "the claimed invention is not supported by none of a specific utility, a well established utility or a substantial utility."

It may be noted in this regard that immunodeficiency diseases are well known to one of ordinary skill in the art to which this invention belongs and the selective absence of serum and secretory IgA is the most common defect (**Rebecca H. Buckley,** Chapter 114, page 689, *Primary Defects of Antibody Production* in Nelson, Textbook of Pediatrics, 17th Edition, Behrman RE, Klegman RM, Jenson HB (Eds), Saunders, Philadelphia 2003). ***Buckley*** goes on to describe various diseases associated with deficiencies in immunoglobulin production. Therefore, monitoring immunoglobulin production by any means is a well established utility that requires no further experimentation. The discovery of immunocoprocytes as described in the present application is novel and facilitates noninvasive assessment of mucosal immunity. Since the invention describes the normal limits of distribution of immunocoprocytes (see Table 2 in the specification), a deviation or suppression of these cells would be, as expected (**Buckley**), provides evidence of the existence of immunodeficiency disease. Furthermore, the cells possessing the various immunoglobulins and the receptors have been characterized (Figure 3), thereby enabling a skilled artisan to use the immunocoprocytes of the present invention for noninvasive assessment of mucosal immunity.

It is believed that without further elaboration the clarification provided above makes the utility of the present invention quite apparent and the rejection under Section 101 should now be withdrawn.

Claims 7-9 and 26-28 stand rejected under Section 112, first paragraph, the examiner noting that "since the claimed invention is not supported by well established utility for the reasons set forth in the rejection under 35 U.S.C. 101 above, one skilled in the art clearly would not know how to use the claimed invention." It is respectfully submitted that in light of the evidence presented above

as to how to use the claimed invention and what utility it serves, the outstanding rejection under Section 112, first paragraph is inapplicable and should now be withdrawn.

It may be pertinent to note here that *Kobayashi et al* mentioned in the Examiner's remarks describes a unique IgG binding Fc receptor in contrast to the discovery of a unique immunoglobulin IgC of the present invention, which is a ***chimera*** consisting of IgA and IgG subunits (Figure 3 in the application). Hence, *Kobayashi et al* is distinct and different from the claimed invention.

The Examiner has further noted at page 9, second paragraph that "As drawn to the "how to make' prong...immunocoprocytes. There is no teaching of the concentration of each of IgC, IgA and Cfc on immunocoprocytes. There is no teaching of the structures of either CFc or IgC."

It may be clarified in this respect that the specification under the title of 'Immunocoprocytes" (page 13 *et seq*) describes several approaches to isolate immunocoprocytes by techniques that one of ordinary skill in the art could use. They include the immune adherence approach, fluorescence-activated cell sorting, and solid matrix capture. The relative distribution of each of these immunoglobulins and CFc is presented in Table 2 and the structures of these components are also diagrammatically presented in Figure 3. The fact that immunocoprocytes bearing only IgG are rare, shows that structurally all of the IgG recognition sites are associated with the chimeric form of immunoglobulin designated as IgC consisting of both IgG and IgA (depicted structurally in Figure 3).

It is believed that these remarks clearly obviate Section 112 rejection.

Claims 7-9 and 26-28 stand rejected under Section 102 as anticipated by *Dutta et al* cited by the Examiner. It may be noted in this regard that the cited prior art *Dutta et al* abstract describes expression of CD44 in colon cancer and has no reference to expression of CFc or about immunocoprocytes. It is not understood, therefore, how Dutta et al anticipates the present invention which is related to immunocoprocytes, a unique cellular entity discovered by the applicant.

Claims 7-9 and 26-28 were further rejected under Section 103 as being obvious over *Kobayashi et al* in view of *Dutta et al* cited by the Examiner. It may be noted that *Kobayashi et al* describes a unique IgG binding Fc receptor in contrast to the discovery of a unique immunoglobulin IgC of the present invention, which is a ***chimera*** consisting of IgA and IgG subunits (Figure 3 in the application), whereas Dutta et al abstract describes expression of CD44 in colon cancer and has no reference to expression of CFc or about immunocoprocytes.

As to the Examiner's assertion that *Dutta et al*'s isolated colonocytes inherently include a subset of colonocytes which express CFc, it may be pointed out that the methodology employed by *Dutta et al* is, first of all, incapable of producing the type and purity of colonocytes as required and obtained by the unique and distinctive isolation process described in the specification of the present invention. Secondly, even if substantially pure isolated colonocytes are obtained, further techniques and processes must be employed to obtain a distinctive group of cells identified as "IMMUNOCOPROCYTES" (described on page 13 of the present specification under the same subheading), which are unique in expressing heretofore unknown **chimeric** immunoglobulin, IgC. Furthermore, the fact that a prior art article **may** inherently have the characteristics of the claimed product is not sufficient. Inherency must be a necessary result, not merely a possible result. **In re Oelrich** (CCPA 1981) 212 USPQ 323. Since immunocoprocytes' nature, properties and characteristics were heretofore not known, it is unimaginable how such unique cells could hav been inherently anticipated. In short, there is no disclosure or teaching in any prior art to inherently anticipate the claimed invention. Hence, the outstanding rejection under 35 U.S.C. 103 is inapplicable and should be withdrawn.

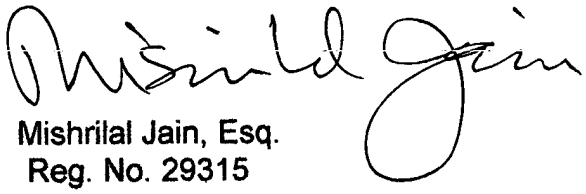
As a further clarification related to utility, additional citations showing the utility of measuring immune function in a variety of diseases are provided herewith (A. Par, Gastrointestinal tract as a part of immune defence in **Gastrointestinal**

Immunology, A. Par, I. Racz, and G. Mozsik (Eds), Akademia Kiado, Budapest 2001.

L. Lakatos, Immunology of inflammatory bowel disease in **Gastrointestinal Immunology,** A. Par, I. Racz, and G. Mozsik (Eds), Akademia Kiado, Budapest 2001). Entry of same is respectfully requested.

In light of the above, the claims are now believed to be in condition for allowance and favorable action accordingly is earnestly solicited. A cheque toward payment of fees for one month extension is enclosed herewith.

Respectfully submitted,



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